

In the United States Court of Federal Claims

No. 16-878

(Filed: April 13, 2022)

Reissued: June 28, 2022¹

DOUGLAS KELLY,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Renée J. Gentry, Vaccine Injury Litigation Clinic, George Washington University Law School, Washington, DC, for petitioner.

Adriana Ruth Teitel, Vaccine/Torts Branch, Civil Division, United States Department of Justice, Washington, DC, for respondent.

OPINION

SMITH, Senior Judge

The Court should take note of the good work of the George Washington University Law School Vaccine Injury Litigation Clinic and its Director Renée J. Gentry, which helps ensure adequate representation for litigants before the Court and the Office of Special Masters. This clinic contributes significantly to the fair and efficient administration of justice at the Court.

Petitioner, Douglas Kelly, seeks review of a decision issued by Chief Special Master Brian H. Corcoran denying his petition for vaccine injury compensation. Petitioner brought this action pursuant to the National Vaccine Injury Compensation Program, 42 U.S.C. §§ 300aa-10, *et seq.* (the “Vaccine Act”), alleging that he suffered sudden hearing loss as a result of receiving the influenza (“flu”) vaccine, which aggravated a preexisting condition. The Chief Special Master denied compensation, finding that petitioner did not support his theory by a preponderance of the evidence. The petitioner also failed to establish that he suffered from any preexisting condition that could be aggravated by the flu vaccine. Petitioner now moves for review of this decision. For the reasons that follow, the Court **DENIES** petitioner’s Motion for Review.

¹ An unredacted version of this opinion was issued under seal on April 13, 2022. The parties were given an opportunity to propose redactions, but no such proposals were made.

I. BACKGROUND AND PROCEDURAL HISTORY

Mr. Kelly's medical history shows that he "suffered no medical conditions" with no medication except Simvastatin to control cholesterol. Petition at 1, ECF No. 1. On September 7, 2015, petitioner received the trivalent flu vaccine. *Id.* Shortly thereafter, petitioner "experienced severe ringing in his ears and a loss of equilibrium." *Id.* Later that day, petitioner was admitted to Rose Medical Center where he was diagnosed with vertigo and sudden hearing loss. *Id.* at 1–2. On September 10, 2015, petitioner met with an Ear, Nose, and Throat Specialist, Dr. Owen Reichman, who diagnosed petitioner with sensorineural hearing loss, unilateral, and sudden hearing loss, unspecified ("SNHL"). *Id.* at 2; *see also* Medical Records, Exhibit 4 (ENT of Denver) at 22–25, ECF No. 5. Dr. Reichman opined that it "was not clear why this occurred after the flu shot [sic] may be related to the activation of antibodies." Petition at 2. On November 30, 2015, Dr. Reichman noted that petitioner's hearing and vertigo had slightly improved, but petitioner still experienced "lightheadedness and intermittent dizziness with quick motion." *Id.* On February 1, 2016, petitioner visited Dr. Reichman who again noted slight improvement, but stated that petitioner's hearing remained "very poor." *Id.* On May 2, 2016, Dr. Reichman noted that petitioner's hearing was "still poor on the left" and would "likely not change." *Id.*

On July 25, 2016, petitioner filed his Petition with the Office of Special Masters, seeking compensation for vaccine-related injuries. *See generally* Petition. On July 26, 2016, this case was assigned to Special Master Hastings. *See* Notice of Assignment to Special Master Hastings, ECF No. 4. On October 5, 2017, this case was reassigned to Special Master Corcoran. Notice of Reassignment to Special Master Corcoran, ECF No. 34. On October 11, 2016, respondent submitted a Vaccine Rule 4(c) Report recommending that compensation not be awarded. *See generally* Respondent's Rule 4(c) Report, ECF No. 10. On December 5, 2017, this case was reassigned to Special Master Oler. Notice of Reassignment to Special Master Oler, ECF No. 36.

On August 5, 2019, petitioner filed a status report, seeking to move forward with a Ruling on the Record and forgo a hearing on entitlement due to the Court's substantially delayed docket. *See* August 5, 2019 Status Report, ECF No. 43. On August 20, 2020, Special Master Oler ordered the parties to file their respective supplemental expert reports responding to questions set forth in the same order. *See* August 20, 2020 Order, ECF No. 55. On October 19, 2020, the parties filed their respective expert reports responding to Special Master Oler's questions. *See generally* Expert Report of Dr. Carlo Tornatore, Attachment 2, ECF No. 56; Expert Report of Dr. Douglas Bigelow, Attachment 1, ECF No. 57.

On January 29, 2021, this case was reassigned for the final time to Chief Special Master Corcoran. Notice of Reassignment, ECF No. 60. On October 18, 2021, the Chief Special Master denied petitioner's claim, finding that petitioner did not establish that he suffered from any preexisting condition that the flu vaccine could aggravate, and that petitioner's causation theory was not preponderantly supported. *See* Ruling on Entitlement at 2, ECF No. 66 [hereinafter Entitlement Decision]. On November 17, 2021, petitioner filed his Motion for Review of Chief Special Master Corcoran's decision with this Court. *See* Motion for Review, ECF No. 68 [hereinafter MFR]. On December 17, 2021, respondent filed its Response to petitioner's Motion

for Review. *See* Respondent’s Response to Petitioner’s Motion for Review, ECF No. 70 [hereinafter Resp. to MFR]. Petitioner’s Motion is fully briefed and ripe for review.

II. STANDARD OF REVIEW

Under the Vaccine Act, this Court may review a Special Master’s decision upon the timely request of either party. 42 U.S.C. § 300aa-12(e)(1)–(2). In reviewing such a request, this Court may:

- (A) uphold the findings of fact and conclusions of law . . . ,
- (B) set aside any findings of fact or conclusion of law . . . found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law . . . , or
- (C) remand the petition to the special master for further action in accordance with the court’s direction.

Id. § 300aa-12(e)(2)(A)–(C). “Fact findings are reviewed . . . under the arbitrary and capricious standard; legal questions under the ‘not in accordance with law’ standard; and discretionary rulings under the abuse of discretion standard.” *Munn v. Sec’y of Dep’t of Health & Hum. Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

On review of a decision, this Court cannot “substitute its judgment for that of the special master merely because it might have reached a different conclusion.” *Snyder v. Sec’y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 718 (2009). This court does not “reweigh the factual evidence, assess whether the special master correctly evaluated the evidence, or examine the probative value of the evidence or the credibility of the witnesses—these are all matters within the purview of the fact finder.” *Porter v. Sec’y of Health & Hum. Servs.*, 663 F.3d 1242, 1249 (Fed. Cir. 2011). “[R]eversible error is extremely difficult to demonstrate if the special master has considered the relevant evidence of record, drawn plausible inferences and articulated a rational basis for the decision.” *Lampe v. Sec’y of Health & Hum. Servs.*, 219 F.3d 1357, 1360 (Fed. Cir. 2000) (internal quotation marks omitted). “[A]s long as a special master’s finding of fact is ‘based on evidence in the record that [is] not wholly implausible, we are compelled to uphold that finding as not being arbitrary or capricious.’” *Porter*, 663 F.3d at 1249 (quoting *Cedillo v. Sec’y of Health & Hum. Servs.*, 617 F.3d 1328, 1338 (Fed. Cir. 2010)).

III. DISCUSSION

The Vaccine Act provides that causation is established through (1) a statutorily prescribed presumption of causation when the injury falls under the Vaccine Injury Table (“table injury”); or (2) proving causation-in-fact when the injury is not listed in the Vaccine Injury Table (“off-table injury”). *Althen v. Sec’y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). To prove causation-in-fact, a petitioner must

show by *preponderant evidence* that the vaccination brought about [petitioner’s] injury by providing: (1) **a medical theory causally connecting the vaccination and the injury**; (2) a logical sequence of cause and effect showing that the

vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id. (emphasis added). Relevant here, for *Althen* prong I—a medical theory causally connecting the vaccination and the injury—petitioners must provide a “reputable medical theory” which demonstrates that the vaccine can cause the type of injury suffered. *Pafford v. Sec’y of Health & Hum. Servs.*, 451 F.3d 1352, 1355–56 (Fed. Cir. 2006) (internal citations omitted). This medical theory must be supported by “sound and reliable medical or scientific explanation” but need not be medically or scientifically certain. *Knudsen v. Sec’y of Health & Hum. Servs.*, 35 F.3d 543, 548–49 (Fed. Cir. 1994). Petitioner must satisfy all three *Althen* prongs to prove causation-in-fact. *See Althen*, 418 F.3d at 1278.

The petitioner’s burden of proof, regardless of whether the injury is a table or non-table injury, is to show by a *preponderance of the evidence* that the vaccine caused the injury. *Id.* The Federal Circuit has interpreted this standard as “one of proof by a simple preponderance or ‘more probable than not’ causation.” *Althen*, 418 F.3d at 1279 (citing *Hellebrand v. Sec’y of Health & Hum. Servs.*, 999 F.2d 1565, 1572–73 (Fed. Cir. 1993)). The purpose of this standard is to “allow the finding of causation in a field bereft of complete and direct proof of how vaccines affect the human body.” *Id.* at 1280.

In cases where the petitioner alleges significant aggravation of a preexisting condition, the *Althen* test is expanded with three additional prongs. *See Loving v. Sec’y of Health & Hum. Servs.*, 86 Fed. Cl. 135, 144 (2009). The petitioner must prove by a *preponderance of the evidence* that the vaccine caused significant aggravation of:

- (1) the person’s condition prior to administration of the vaccine, (2) the person’s current condition (or the condition following the vaccination if that is also pertinent), (3) whether the person’s current condition constitutes a ‘significant aggravation’ of the person’s condition prior to vaccination, (4) **a medical theory causally connecting such a significantly worsened condition to the vaccination**, (5) a logical sequence of cause and effect showing that the vaccination was the reason for the significant aggravation, and (6) . . . a proximate temporal relationship between the vaccination and the significant aggravation.

Id. (emphasis added). In sum, the *Loving* test incorporates all three *Althen* prongs, but also requires the petitioner to show that they experienced a significant aggravation of a preexisting condition. *See id.*

It is within this framework that petitioner makes two objections to the Chief Special Master’s Entitlement Decision. Petitioner asserts that the Chief Special Master (1) improperly heightened petitioner’s burden of proof by requiring confirmation or certainty regarding the validity of the specific legal theory of causation set forth in the medical literature; and (2) abused his discretion by reassigning the case to himself after the Motion for Ruling on the Record was filed. *See generally* MFR. Petitioner argues that these actions by the Chief Special Master were arbitrary and capricious, an abuse of discretion, and contrary to law. *Id.*

A. Burden of Proof

In his Motion for Review, petitioner alleges *inter alia* that the Chief Special Master improperly heightened petitioner's burden of proof. See MFR at 15–19. In *Andreu v. Secretary of Health and Human Services*, the Federal Circuit held that *Althen* prong I can be satisfied by presenting a “biologically plausible” theory. *Andreu v. Sec’y of Health & Hum. Servs.*, 569 F.3d 1367, 1376–79 (Fed. Cir. 2009). The Court expressly rejected requiring proof of confirmation of medical plausibility from the medical community and literature. *Id.* Petitioner argues that the Chief Special Master misapplied *Andreu*’s “biological plausibility” standard under *Althen* prong I and required *confirmation or certainty* of the validity of the specific theory of causation in the medical literature. MFR at 15–17. Petitioner argues that the Chief Special Master’s error was “due substantially to his reliance on an epidemiological study [i.e. the Baxter Study] that did not rule out causation between vaccination and rare incidence of SNHL.” *Id.* at 17. Petitioner argues that the Chief Special Master misconstrued the evidentiary importance of epidemiological studies and argues that petitioner’s causal theory need only be “plausible in the case at hand” and “not for the average recipient of a vaccine.” *Id.* at 18.

Respondent argues that, as an initial matter, petitioner did not satisfy *Althen* prongs II and III, so the Court need not address “petitioner’s evidence, or the lack thereof, under *Althen* prong one/*Loving* prong four.” Resp. to MFR at 14 (internal citation omitted). Respondent also argues that petitioner failed to establish that he suffered from a preexisting microvascular angiopathy, “a fact central to his significant aggravation claim.” *Id.* Regardless, respondent argues that the Chief Special Master applied the appropriate legal standard, and petitioner is incorrect that he need only “demonstrate biologic plausibility to satisfy *Althen* prong one” because petitioner must show such plausibility by a *preponderance of the evidence*. *Id.* at 15 (citing MFR at 16). Additionally, respondent argues the Chief Special Master’s consideration of the Baxter study was appropriate among a careful consideration of the entire record, including the parties’ expert reports, medical studies, and case reports cited therein. Resp. to MFR at 19. Respondent posits that the Chief Special Master “appropriately considered the qualifications and expertise of the parties’ experts on the key issues of the case: immunology and otolaryngology.” *Id.*

Here, the record does not support petitioner’s argument that the Chief Special Master improperly heightened petitioner’s burden of proof though a misapplication of law. The Chief Special Master applied the correct legal test for *Althen* prong I: petitioners must (1) provide a “reputable medical theory” demonstrating that the vaccine can cause the type of injury alleged; and (2) meet their burden of proof by a preponderance of the evidence. Entitlement Decision at 24; see also *Knudsen*, 35 F.3d at 548–49. The Chief Special Master considered petitioner’s medical theory and analyzed whether petitioner met his evidentiary burden under that theory. See Entitlement Decision at 35–37. The Chief Special Master concluded that the evidence offered under *Althen* prong I/*Loving* prong IV “failed to clear the preponderant line” and provided ample reasons for why petitioner fell short. *Id.* at 35.

The Chief Special Master considered the record and found “limited to nonexistent” evidence connecting the flu vaccine specifically to SNHL. See *id.* at 36 (noting that petitioner provided a few case reports which had low probative weight in comparison to reliable epidemiologic articles like Baxter) (internal citations omitted). The Chief Special Master also

found the petitioner’s expert Dr. Carlo Tornatore’s opinion unpersuasive. *Id.* at 35–36. Dr. Tornatore presented a theory that petitioner experienced a rapid Type I sensitivity reaction that could exacerbate a vascular condition in petitioner’s ear. *Id.* at 35. The Chief Special Master found this theory lacking because (1) petitioner had to show that he possessed a preexisting condition, which was not preponderantly demonstrated, and (2) Dr. Tornatore did not show how his theory—that vaccines could cause *other* hypersensitivity reactions or that *distinguishable* ear-oriented illnesses could cause hearing loss—would cause *the flu vaccine* to worsen a preexisting condition in this case. *Id.* at 36 (stating that Dr. Tornatore’s theory failed to show how the flu vaccine would worsen a preexisting condition “by the same mechanism applicable to a different kind of illness.”).

Finally, the Chief Special Master found petitioner’s alternative argument—that his hearing loss could be driven by an autoimmune process—unconvincing based on the timeline and the resulting unilateral hearing loss (i.e., hearing loss in one ear). *Id.* As the Chief Special Master stated, petitioner’s onset of symptoms was “entirely too short to be deemed medically acceptable.” *Id.* at 34 (explaining that under the causal mechanism proposed, the evidence offered does not preponderantly support the conclusion that the flu vaccine could prompt acute hearing loss so quickly). Further, the Chief Special Master found that if petitioner’s SNHL was driven by an autoimmune process, it would likely present itself as bilateral hearing loss (i.e., in both ears). *Id.* at 36. The Chief Special Master found respondent’s expert, Dr. Douglas Bigelow, convincing in that hearing loss with a vascular origin would similarly progress to a complete loss of hearing. *See id.* Thus, the Chief Special Master concluded that petitioner failed to preponderantly establish that the flu vaccine could cause SNHL.

As it is a requirement that petitioner demonstrate preponderately a medical theory supported by “sound and reliable medical or scientific explanation,” the Chief Special Master did not act contrary to law when he concluded that petitioner did not preponderantly satisfy *Althen* prong I/Loving prong IV. *See Knudsen*, 35 F.3d at 548–49. The record demonstrates that the Chief Special Master weighed the evidence before him and reasonably determined that petitioner had not met his burden of proof. Accordingly, the Court finds that the Chief Special Master’s findings are not arbitrary or capricious, an abuse of discretion, or contrary to law.

B. Reassignment to the Chief Special Master

Petitioner also argues that the Chief Special Master abused his discretion when he reassigned this case to himself from the previous Special Master *after* the Motion for Ruling on the Record was filed. MFR at 11. Specifically, petitioner argues that he was denied due process when the Chief Special Master reassigned the case after “the bulk of the proceedings” had been conducted in front of Special Master Oler and after petitioner filed his Motion for Ruling on the Record “addressing Special Master Oler’s questions and[] drafted in light of Special Master Oler’s prior decisions.” *Id.* at 11–12. In changing the Special Master, petitioner claims that he was denied “his right of presenting his case in a meaningful manner” and “denied fundamental fairness in his proceedings.” *Id.* at 12 (citing *Campbell ex. Rel. Campbell v. Sec’y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 778 (2006)).

In response, respondent argues that Vaccine Rule 3(d) allows the Chief Special Master to reassign cases “for the efficient administration of justice.” *Id.* at 12. Additionally, respondent argues that petitioners have no right to an entitlement hearing in the Vaccine Program in the first place and the decision to conduct one “lies firmly within the discretion of the special master.” *Id.* at 13.

Petitioner has not presented any evidence to substantiate his claims that the Chief Special Master’s reassignment resulted in a denial of due process and therefore infringed his rights. The Vaccine Act states that a special master “may conduct such hearings as may be reasonable and necessary.” See 42 U.S.C. § 300aa-12(d)(3)(B)(v). This gives special masters “wide discretion in conducting the proceedings in a case.” *Burns v. Sec’y of Dep’t of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993). Such discretion includes the special master’s decision not to hold an evidentiary hearing. See *Kreizenbeck v. Sec’y of Health & Hum. Servs.*, 141 Fed. Cl. 138 (2018). The Vaccine Rules were promulgated not to require the “routine use of oral presentations, cross examinations, or hearings.” *Kreizenbeck*, 141 Fed. Cl. at 139–40 (citing 42 U.S.C. § 300aa-12(d)(2)(D)). If the special master affords a party “a full and fair opportunity to present its case,” it is permissible to proceed with a ruling on the record. *Spahn v. Sec’y of Health & Hum. Servs.*, 133 Fed. Cl. 588, 600 (2017). In any event, petitioner himself chose to forgo a hearing in this case. See August 5, 2019 Status Report, ECF No. 43. But even if he did not, petitioners have no right to an evidentiary hearing. See *Caron v. Sec’y of Health & Hum. Servs.*, 136 Fed. Cl. 360, 386 (2018) (internal citations omitted). Accordingly, a special master’s discretionary decision to proceed without a hearing is not a denial of a guaranteed procedural right. *Id.*

The Chief Special Master acted within his discretion when he reasonably decided to proceed without a hearing, and he provided ample reasons why he believed this claim could be fairly resolved without a hearing. See Entitlement Decision at 37. The Chief Special Master determined that this claim could be fairly resolved without live testimony from experts because the “SNHL injury was not disputed, nor the facts pertaining to its onset, leaving only the causation theory and the alleged preexisting condition to be determined.” *Id.* The Chief Special Master noted that there were several rounds of expert-report submissions and articles filed which resulted in a “fairly well-developed record.” *Id.* Accordingly, the Chief Special Master determined that “live testimony from experts would not have altered the outcome, as [he] could understand the nature of the experts’ disagreement based on the written record itself.” *Id.*

Finally, the Court finds no support for the allegations that petitioner was uniquely targeted by the Chief Special Master for an adverse ruling. Vaccine Rule 3(d) allows the Chief Special Master to reassign cases to another special master for the efficient administration of justice. Petitioner does not dispute this authority. See MFR at 12 (acknowledging that “when necessary for the efficient administration of justice, the chief special master may reassign the case to another special master.”). On or around the time of this case’s reassignment to the Chief Special Master, several other cases were reassigned from Special Master Oler and Special Master Roth. See Resp. to MFR at 12, nn. 6–7 (citing “*Fantini* 15-1332V; *Houston* 18-420V; *Martinez* 16-738V; *Riley* 15-104V; and *Ulysse* 15-451V” as well as “*Bechel* 16-887V; *Bielak* 18-761V; *Dennington* 18-1303V; *Grossmann* 18-13V; *Humphries* 17-288V; *Kalajdzic* 17-792V; and

Porch 17-802V.”). These reassignments appear to be routine case management and within the ambit of Vaccine Rule 3(d).

The Court must also take note of the fact that legislation is pending to expand the number of special masters from eight to sixteen. Currently, the Special Masters have an extraordinarily heavy docket given the complexity of their cases. The Chief Special Master is to be commended for using reassignments to balance the overloaded docket to create greater efficiency. Sometimes this results in unfortunate shuffling of cases.

Therefore, the Court finds that the Chief Special Master did not abuse his discretion when he decided to rule on the record without a hearing. The Court need not address the remaining arguments as they are without merit.

IV. CONCLUSION

For the foregoing reasons, the Court finds that the Chief Special Master did not act arbitrarily or capriciously, contrary to law, or abuse his discretion. Accordingly, the Court upholds the Chief Special Master’s decision and **DENIES** petitioner’s Motion for Review.

IT IS SO ORDERED.

s/ *Loren A. Smith*

Loren A. Smith,
Senior Judge